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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,561	12/12/2003	David James Dooley	PC 25627A	3925

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WARNER-LAMBERT COMPANY
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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,561	DOOLEY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9,11-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 7, 9 and 11-12 are presented for examination.

Applicant's Amendment filed September 7, 2006 has been received and entered into the present application.

Claims 7, 9 and 11-12 are pending and under examination. Claims 1-6, 8, 10 and 13-16 are cancelled and claims 7, 9 and 11-12 are amended.

Applicant's arguments, filed September 7, 2006, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 9 and 11-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bryans et al. (WO 99/21824; 1999) in view of Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th Edition, pages 481-482), each already of record, for the reasons of record set forth at pages 5-6 of the previous Office Action dated June 7, 2006, of which said reasons are herein incorporated by reference.

Applicant traverses the present rejection by alleging that, though Bryans et al. teaches the use of (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid for the treatment of pain, *The Merck Manual* teaches away from the use of a pain reliever for treating fibromyalgia. Applicant relies upon the fact that *The Merck Manual* teaches at page 482, "[a]spirin 650 mg po q 3 to 4 h or other NSAIDs in full dosages have not generally been shown to be effective in clinical trials but may help individual patients." Please see page 6 of Applicant's remarks. Applicant further submits that *The Merck Manual* teaches the use of low-dose tricyclic antidepressants, injections of lidocaine in combination with a hydrocortisone acetate suspension, and/or the use of a serotonin-specific reuptake inhibitor to help alleviate depression and help symptoms of fibromyalgia, but fails to suggest that, at present, any particular drug, including an analgesic, would be useful in treating fibromyalgia.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, it is noted that *The Merck Manual* clearly teaches the presence of pain in patients suffering from fibromyalgia. Please see *Merck*, pages 481-482. Such a teaching clearly raises the reasonable expectation that employing a therapeutic directed to treating pain in a patient suffering from fibromyalgia would necessarily ameliorate the overall condition of fibromyalgia, absent factual evidence to the contrary, since pain is a symptom of fibromyalgia.

Accordingly, the fact that Bryans et al. teaches the claimed (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid for the treatment of pain and *Merck* teaches the clear occurrence of pain in patients suffering from fibromyalgia raises the reasonable expectation that the claimed (3S,4S)-(1-

aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid would be capable of ameliorating the pain associated with fibromyalgia as a result of its known analgesic effects as taught by Bryans et al. Though the prior art may not have previously recognized the use of the claimed compound for the treatment of fibromyalgia *per se*, a compound and its properties are inseparable such that any analgesic effect that the claimed compound would have in treating the pain associated with fibromyalgia would have necessarily been useful for, and ameliorated, the overall condition of fibromyalgia, absent factual evidence to the contrary. In other words, the efficacy of (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid in treating pain, a symptom of fibromyalgia, would have necessarily treated fibromyalgia *per se* because the treatment and/or elimination of specific symptoms known to occur with such a condition would have been reasonably expected to improve the condition as a whole.

Though Applicant alleges that *Merck* teaches away from the use of a pain reliever for treating fibromyalgia based upon the fact that aspirin has not been shown to be effective in clinical trials, such a teaching fails to constitute a teaching away from the use of an analgesic. First, *Merck* teaches that aspirin or other NSAIDs are not *generally* effective in treating the pain associated with fibromyalgia, but does explicitly state that they *may show efficacy* in some patients. In other words, *Merck* does not completely discount the usefulness of an analgesic therapy for pain management in fibromyalgia subjects. Accordingly, such a statement does not amount to a generalized conclusion that analgesics would not be at all useful in the treatment of pain associated with fibromyalgia. Rather, *Merck* merely teaches that aspirin and other NSAIDs are not necessarily an optimal course of treatment for the majority of subjects suffering from pain resulting from fibromyalgia.

Furthermore, Applicant relies upon the less than optimal pain management efficacy of aspirin and other NSAIDs in treating fibromyalgia pain as the basis for concluding that the (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid compound would also not have efficacy in treating fibromyalgia pain. However, Applicant has extrapolated the efficacy from a specific genus of analgesics (i.e., aspirin

and NSAIDs) to a specific species of medication (i.e., the compound of Bryans et al.) without providing any reasoning or evidence to support such a conclusion as to why one of ordinary skill in the art at the time of the invention would have expected similar efficacy, or lack thereof, using the compound taught by Bryans et al. Generic allegations that aspirin or other NSAIDs are not particularly effective for ameliorating fibromyalgia pain fail to establish any basis for extrapolating such a conclusion to the claimed compound [i.e., that taught by Bryans et al.; (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid], since aspirin and NSAIDs have a distinctly different mechanism of action than the claimed compound. In fact, this different mechanism of action alone would have been supportive of a conclusion that the two compounds would have been reasonably expected to differ in activity such that the efficacy seen with one type of analgesic would *not* necessarily have been suggestive of the same, or even substantially similar, efficacy with a completely different type of analgesic in the absence of any reasoning or evidence to support such a conclusion. Accordingly, Applicant's arguments that *Merck* teaches away from the use of an analgesic for fibromyalgia based upon the less than optimal efficacy of aspirin and other NSAIDs for the same purpose are clearly not persuasive.

Additionally, Applicant's submission that *Merck* teaches a variety of other therapies for treating fibromyalgia, but fails to suggest the use of an analgesic, is not germane to the basis of the rejection. *Merck* was relied upon for its teaching of pain associated with fibromyalgia and Bryans et al. teaches the analgesic effects of (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid. Clearly Bryans et al. and *Merck* taken in combination provide a reasonable expectation of success in treating the pain associated with fibromyalgia using the analgesic compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid, absent factual evidence to the contrary. As noted *supra*, the treatment of symptom(s) known to be present in the syndrome of fibromyalgia, such as pain, would have necessarily ameliorated the condition as a whole. Applicant has failed to provide any reasoning or evidence of record as to why one of ordinary skill in the art at the time of the invention would not have reasonably expected

the compound of Bryans et al. to treat the specific type of pain associated with fibromyalgia. Accordingly, the claimed subject matter remains obvious over the cited prior art for the reasons of record and those set forth *supra*.

For these reasons, and those previously made of record at pages 5-6 of the previous Office Action dated June 7, 2006, rejection of claims 7, 9 and 11-12 remains proper and is **maintained**.

Double Patenting (New Grounds of Rejection)

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional Rejection

Claims 7, 9 and 11-12 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending U.S. Patent Application No. 10/935,824; or claim 2 of copending U.S. Patent Application No. 11/675,389; each alternatively in view of Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th Edition, pages 481-482).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited copending applications are not considered patentably distinct from each other because the present claims are rendered obvious by the copending claims.

The copending claims clearly provide for the administration of an alpha-2-delta ligand compound in a therapeutically effective amount for the treatment of pain, wherein the alpha-2-delta ligand may be, e.g., the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid (see, e.g., the '824 application at p.8, l.8-22; or the '389 application at p.28). Though the copending claims do not specifically recite the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid, the specification is relied upon at the sections cited *supra* for a definition of the alpha-2-delta ligands that are within the scope of the claimed genus. Such reliance on the specification for this purpose is in accordance with the MPEP at §804(II)(B)(1), which states, "The specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)...Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent."

Though the copending claims do not specifically recite the treatment of fibromyalgia, Beers et al. is cited for its teachings that the ailment of fibromyalgia is characterized by pain of the fibrous tissues, muscles, tendons, ligaments and other sites (p.482-482). Beers et al. further teaches that fibromyalgia may be generalized (sometimes associated with a concomitant condition), such as, e.g., with the symptoms or conditions of poor sleep, anxiety, fatigue and/or irritable bowel syndrome (p.482). In view of such teachings, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ the alpha-2-delta ligand compound for the treatment of the pain occurring in fibromyalgia, since the copending claims clearly teach the analgesic effects of such a compound(s) and, therefore, raise the reasonable expectation that the same compounds would ameliorate the pain associated

with fibromyalgia, absent factual evidence to the contrary.

Accordingly, rejection of claims 7, 9 and 11-12 is proper over claim 16 of copending U.S. Patent Application No. 10/935,824 or claim 2 of copending U.S. Patent Application No. 11/675,389, as claiming obvious and unpatentable variants thereof. This is a provisional rejection because the claims have not yet, in fact, been patented.

Claims 7, 9 and 11-12 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of copending U.S. Patent Application No. 11/688,001 in view of Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th Edition, pages 481-482).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited copending applications are not considered patentably distinct from each other because the present claims are rendered obvious by the copending claims.

The copending claim clearly provides for the administration of an alpha-2-delta ligand compound in a therapeutically effective amount for the treatment of fibromyalgia, wherein the alpha-2-delta ligand may be, e.g., the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid (see, e.g., p.28). Though the copending claim does not specifically recite the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid, the specification is relied upon at the page cited *supra* for a definition of the alpha-2-delta ligands that are within the scope of the claimed genus. Such reliance on the specification for this purpose is in accordance with the MPEP at §804(II)(B)(1), which states, "The

specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)...Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent."

Though the copending claim does not specifically recite the treatment of a concomitant condition, such as, e.g., irritable bowel syndrome, etc., Beers et al. is cited for its teachings that the ailment of fibromyalgia is characterized by pain of the fibrous tissues, muscles, tendons, ligaments and other sites (p.482-482). Beers et al. further teaches that fibromyalgia may be generalized (sometimes associated with a concomitant condition), such as, e.g., with the symptoms or conditions of poor sleep, anxiety, fatigue and/or irritable bowel syndrome (p.482). In view of such teachings, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ the alpha-2-delta ligand compound for the treatment of the fibromyalgia with a reasonable expectation that the patient suffering from fibromyalgia would also be suffering from a concomitant disorder, such as, e.g., irritable bowel syndrome, since Beers et al. clearly teaches the association of such conditions with fibromyalgia. Accordingly, such a teaching is supportive of the conclusion that patients with fibromyalgia would likely be suffering from such additional ailments and, thus, such ailments would also be treatable via the (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid.

Accordingly, rejection of claims 7, 9 and 11-12 is proper over claim 21 of copending U.S. Patent Application No. 11/688,001, as claiming obvious and unpatentable variants thereof. This is a provisional rejection because the claims have not yet, in fact, been patented.

Non-Provisional Rejection

Claims 7, 9 and 11-12 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,635,673 (2003) in view of

Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th Edition, pages 481-482).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited patent are not considered patentably distinct from each other because the pending claims are rendered obvious by the patented claims.

The patented claims clearly provide for the administration of the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid in a therapeutically effective amount for the treatment of pain. Though the copending claims do not specifically recite the treatment of fibromyalgia, Beers et al. is cited for its teachings that the ailment of fibromyalgia is characterized by pain of the fibrous tissues, muscles, tendons, ligaments and other sites (p.482-482). Beers et al. further teaches that fibromyalgia may be generalized (sometimes associated with a concomitant condition), such as, e.g., with the symptoms or conditions of poor sleep, anxiety, fatigue and/or irritable bowel syndrome (p.482). In view of such teachings, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ the alpha-2-delta ligand compound for the treatment of the pain occurring in fibromyalgia, since the copending claims clearly teach the analgesic effects of such a compound(s) and, therefore, raise the reasonable expectation that the same compounds would ameliorate the pain associated with fibromyalgia, absent factual evidence to the contrary.

Accordingly, rejection of claims 7, 9 and 11-12 is proper over claims 1 and 9 of U.S. Patent No. 6,635,673 as claiming obvious and unpatentable variants thereof.

Conclusion

Rejection of claims 7, 9 and 11-12 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

July 10, 2007

Ardin H. Marschel 7/14/07
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SUPERVISORY PATENT EXAMINER